IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellants:	Michael T. Lotze *et al.*
Title:	*METHODS AND REAGENTS FOR INDUCING IMMUNITY*
Appl. No.:	10/688,845
Filing Date:	10/15/03
Examiner:	Amy E. Juedes
Art Unit:	1644
Confirmation Number:	9535

REPLY TO EXAMINER'S ANSWER PURSUANT TO 37 C.F.R. § 41.41

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Sir:

This reply brief is being filed pursuant to 37 C.F.R. § 41.41 in response to the Examiner's Answer dated April 30, 2009. It is timely filed because it is being submitted within two months of the mailing date of the Examiner's Answer.

Appellants submit with this reply brief a Request for Oral Hearing along with the fee set forth in 37 C.F.R. § 41.20 pursuant to 3 C.F.R. § 41.47(b).

No fees are believed to be due. But if any fees are necessary to timely file this reply brief, authorization is hereby given to charge any deficiency and to credit any balance to the undersigned deposit account 19-0741.

ARGUMENT

The Examiner makes two arguments supporting the rejections, both of which are fatally flawed. First, the Examiner admits that the prior art does not teach the therapeutic compositions but contends that the preamble, a "therapeutic composition," "carries little patentable weight" such that the claims read on any composition having the recited components so long as the prior-art composition "is not incompatible with biological activity." This contention is legal error, because the preamble is not a mere intended use. The preamble imparts life and meaning to the claims by limiting the claimed compositions to a discrete subset of compositions. Second, the Examiner argues that the prior art compositions are "physiologically compatible." This factual conclusion lacks support and is refuted by the Declaration Under 37 C.F.R. § 1.132 of Michael T. Lotze. Because both arguments offered in support of the rejections are flawed, the rejections should be reversed for two independent reasons.

A. "Therapeutic Composition" Limits The Claims

The preamble limits the claims, as described in detail in Appellants Brief. Generally, the specification is replete with references to the therapeutic importance of the claimed invention, and these references make clear that the claims are not directed to any cultures, but rather, "therapeutic compositions" to treat tumors. *See Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 U.S.P.Q.2d 1962 (Fed. Cir. 1989) (holding that preamble was limiting because to hold otherwise would be "divorced from reality" in view of specification); *Poly-America, L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1310, 72 U.S.P.Q.2d 1685 (Fed. Cir. 2004) (holding preamble limiting as "important characteristic of claimed invention" based on specification "replete with references" to the preamble). Moreover, claims 27 and 36 recite "a physiologically acceptable solution or buffer" and "a pharmaceutically acceptable carrier," respectively, and this language would be nonsensical unless the claimed compositions are "therapeutic compositions." *Aventis Pharms., Inc. v. Barr Labs., Inc.*, 341 F. Supp. 2d 502, 509 (D.N.J. 2004) (holding "pharmaceutical composition" in preamble to be limiting). Finally, Appellants have repeatedly relied on and continue to rely on the "therapeutic composition" language to distinguish the prior art, which

discloses cell cultures with no suggestion of therapeutic applicability. *In re Sullivan*, 498 F.3d 1345, 1353, 84 U.S.P.Q.2d 1034 (Fed. Cir. 2007) (holding that Board erred in refusing to consider "a use [recited in the preamble] and [an] unexpected property"). Reliance on a preamble to distinguish the prior art transforms the preamble to a limitation. *See Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808, 62 U.S.P.Q.2d 1781 (Fed. Cir. 2002) ("clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation"); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1348, 64 U.S.P.Q.2d 1202 (Fed. Cir. 2002) (holding preamble to be a limitation based on "a clear reliance by the patentee on the preamble" to distinguish the prior art).

Thus, "therapeutic composition" is not a mere intended use but rather is a limitation that breathes life and meaning into the claims. Treating the preamble as a mere intended use would be "divorced from reality," in view of the consistent description of "therapeutic" compositions in the specification and reliance on "therapeutic composition" to distinguish over the prior art.

In refusing to treat the preamble as limiting, the Examiner relies on a fallacy, namely, that the preamble does not impart any structural limitations to the claims. The preamble, however, circumscribes the claims by restricting them to only "therapeutic" compositions rather than all compositions, and the evidence of record shows that "therapeutic" compositions have specific attributes. Namely, one of skill in the art would understand a "therapeutic composition" to be "a composition suitable for administration to a patient for the treatment of some disease or condition." Lotze Decl. at ¶ 7[1]. Such compositions "are formulated so as to preserve the stability of the active agents while making the composition physiologically compatible." *Id.* Thus, "therapeutic compositions" include active ingredients that are formulated so "that they can be safely administered to patients." The formulation may include one of more carriers, buffers, excipients, and tonifiers, for example, depending on the particular dosage form and route of administration, for example.

[1] Declaration Under 37 C.F.R. § 1.132 of Michael T. Lotze filed 29 June 2007.

Appellants cannot simply amend the claims to add specific ingredients that can be included in the therapeutic compositions without unduly limiting the scope of the claims. Therapeutic compositions can contain any combination of carriers, buffers, excipients, and tonifiers, for example, so it is not feasible to list all possible ingredients and combinations without unduly limiting the scope of the claims. And it is not necessary to do so, because one of skill in the art understands that any combination of ingredients can be included to form a composition that "can be safely administered to patients" and that also "preserve[s] the stability o the active ingredients." Accordingly, the preamble adds structural limitations to the claims that cannot be effectively reproduced by simply enumerating additional components.

B. The Prior Art Does Not Teach The Claimed "Therapeutic Composition"

The evidence of record contradicts the Examiner's factual conclusion that the prior art compositions are "physiologically compatible." Even if accurate, moreover, this factual conclusion cannot support the rejection based on a reasonable claim construction.

One of skill in the art would not understand the cultures of Bhardwaj and Kelleher to be "physiologically compatible." Bhardwaj and Kelleher disclose cell cultures developed in the course of general scientific research, and Dr. Lotze, a practicing physician and researcher with over thirty years of experience, opined that these cultures would not be "compatible with physiological conditions." Lotze Decl. at ¶ 10. Because "[t]hese raw cell cultures [] contain contaminants and impurities that may cause potentially serious reactions in patients," no responsible physician would simply administer them to a patient for a therapeutic purpose. *Id.* Accordingly, one of skill in the art would not consider raw cultures intended to evaluate the role of IL-12 in generating cytolytic T lymphocyte (CTL) responses to influenza virus and to determine "whether IL-12 administration during DC maturation altered cell numbers, phenotype and function" to be "physiologically compatible."

The Examiner disregards Dr. Lotze's reasoned opinions, because two of the examples of impurities, IL-10 and TGF-β, "would not render a solution to be physiologically incompatible," as evidenced by their recitation in a dependent claim. IL-10 and TGF-β,

however, are merely two illustrative examples of "inhibitory proteins." Dr. Lotze's opinions however are not limited to IL-10 and TGF-β. Dr. Lotze opines that the cultures would also have "contaminants and impurities that may cause potentially serious reactions in patients" and "inhibitory proteins," both known and unknown, other than IL-10 and TGF-beta. Lotze Decl. at ¶ 10. Due to the presence of these contaminants, impurities, and inhibitory proteins, "a physician would not consider the cell cultures of Bhardwaj and Kelleher to be suitable for use [as] 'therapeutic composition[s].'" *Id.* The Examiner fails to provide any explanation as to why these opinions are flawed and focuses solely on the two illustrative examples of inhibitory proteins. Because the Examiner has failed to provide any explanation as to why Dr. Lotze's reasoned opinions are incorrect, the Examiner's factual conclusion that the prior art compositions are "physiologically compatible" lacks evidentiary support, and in fact, is contradicted by the evidence of record.

To the extent that the Examiner contends that physiological compatibility suffices to render a composition a "therapeutic composition" even if the preamble is considered limiting, the conclusion is premised on an unreasonable claim construction. One of skill in the art understands that a "therapeutic composition" is a composition suitable for administration to a patient for the treatment of some disease or condition. Lotze Decl. at ¶¶ 7, 9. Thus, even if cell culture may be "physiologically compatible," one of skill in the art would not necessarily understand that culture to be a "therapeutic composition." In order to be a "therapeutic composition," there must be some indication that the composition should actually be used in that manner (i.e. administered to a patient). *Id.* Accordingly, the broadest reasonable construction of "therapeutic composition" requires something more than mere physiological compatibility.

CONCLUSION

Appellants respectfully request that the rejections of claims 27-29, 31, 35-38 and 40 be reversed, because the rejections are unsupported by the law or the evidence of record.

Respectfully submitted,

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